

# Analysis of patient reported outcome after correction of sagittal synostosis

No registrations found.

|                              |                            |
|------------------------------|----------------------------|
| <b>Ethical review</b>        | Not applicable             |
| <b>Status</b>                | Pending                    |
| <b>Health condition type</b> | -                          |
| <b>Study type</b>            | Observational non invasive |

## Summary

### ID

NL-OMON25313

### Source

NTR

### Health condition

Sagittal synostosis, patient related outcome measure, surgery

## Sponsors and support

**Primary sponsor:** Erasmus University Medical Center

**Source(s) of monetary or material Support:** no funding

## Intervention

## Outcome measures

### Primary outcome

response to questionnaire, represented and analysed on ordinal scale. Correlation with cranial index and photographic outcome score.

### Secondary outcome

correlation with age at surgery, type of intervention, signs and symptoms of raised intracranial pressure

# Study description

## Background summary

Analysis of Patient Reported Outcome Measure after correction for sagittal suture synostosis and validation with other outcome parameters.

Early closure of the sagittal suture results in restricted growth of the skull width and compensatory growth of the skull length. The resulting head shape is called scaphocephaly. Surgical remodeling of the skull is performed within the first year of life for functional and cosmetic reasons (1).

Cosmetic results are difficult to score in an objective fashion.

An important method to assess cosmetic results is to ask the patient about their satisfaction with the cosmetic results in a standardized questionnaire called Patient-Reported Outcome Measure (PROM)(2).

The goal of this study is to develop an outcome parameter that adequately reflects the patient's appreciation of the cosmetic result of remodeling. The questionnaire consists of 10 questions to be answered on a 5 point scale. The PROM will be validated with other outcome parameters like Cranial Index and photographic scores.

The PROM will be sent to patients between 6 and 18 years old who underwent surgery in their first year of life in the Dutch Craniofacial Center for sagittal suture synostosis.

## References

1. Wong KW, Forrest CR, Goodacre TE, Klassen AF. Measuring outcomes in

craniofacial and pediatric plastic surgery. Clinics in plastic surgery. 2013 Apr;40(2):305-12.

2. Pusic AL, Lemaine V, Klassen AF, Scott AM, Cano SJ. Patient-reported outcome measures in plastic surgery: use and interpretation in evidence-based medicine. Plastic and reconstructive surgery. 2011 Mar;127(3):1361-7.

### **Study design**

One observation between the age of 6 and 18 years

### **Intervention**

1 questionnaire

## **Contacts**

### **Public**

Neurosurgeon <br>  
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M.L.C. Veelen, van  
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### **Scientific**

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## **Eligibility criteria**

### **Inclusion criteria**

patients who underwent correction for sagittal synostosis at the dutch craniofacial study and are momentarily between 6 and 18 years old.

## Exclusion criteria

Patients that do not meet the age criteria to fill in the questionnaire.

Patients with complex synostosis.

## Study design

### Design

Study type: Observational non invasive

Intervention model: Other

**Control:** N/A , unknown

### Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-10-2014

Enrollment: 120

Type: Anticipated

## Ethics review

Not applicable

Application type: Not applicable

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

### Register

NTR-new

NTR-old

Other

### ID

NL4554

NTR4697

: MEC-2014-445

## Study results